
EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel.
MICHAEL S. LORD,

Plaintiffs/Relator,

vs.

NORTH AMERICAN PARTNERS IN
ANESTHESIA, LLP, NAPA
MANAGEMENT SERVICES
CORPORATION, NORTH AMERICAN
PARTNERS IN ANESTHESIA
(PENNSYLVANIA), LLC, and
POCONO MEDICAL CENTER,

Defendants.

Civil Action No. 3:13-CV-2940

(JUDGE MANNION)

ELECTRONICALLY FILED

DECLARATION OF DAVID M. VAUGHN

I, David M. Vaughn, make this declaration in support of the Motion to Dismiss submitted in this matter by defendants NAPA Management Services Corporation and North American Partners in Anesthesia (Pennsylvania), LLC (collectively, "NAPA"). I hereby state as follows:

1. I am over 18 years of age and competent to testify herein. I make this declaration based on my own personal knowledge and pursuant to 28 U.S.C. § 1746.

2. I am an attorney with Vaughn & Associates, LLC, located at 9191 Siegen Lane, Building 8, Baton Rouge, Louisiana, and focus primarily on health

care related legal and compliance issues, including issues involving Medicare coding, billing and reimbursement.

3. I have represented NAPA for a number of years on a variety of matters.

4. The Centers for Medicare and Medicaid Services (“CMS”) is the agency responsible for administering the Medicare program. CMS contracts with private entities known as Medicare Administrative Contractors (“MAC”) to assist in administering Medicare. Each MAC is awarded a geographic jurisdiction to process Medicare Part A and/or Part B (A/B) medical claims for Medicare Fee-For-Service (FFS) beneficiaries. MACs generally serve as the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program.

5. Novitas Solutions, Inc. (“Novitas”), formerly known as Highmark Medicare Services Inc. (“Highmark”), is the MAC responsible for MAC Jurisdiction L, formerly known as Jurisdiction 12, which includes Pennsylvania, New Jersey, Maryland, Delaware and the Washington D.C. Metro Area. Novitas was awarded the contract for Jurisdiction L in late 2007, and has remained the MAC for that jurisdiction since that time.

6. CMS maintains information on its website about the current and former MACs responsible for the various MAC jurisdictions. Attached as **Exhibit**

A is a true and correct copy of the A/B MAC Jurisdiction L Award Fact Sheet, which describes the history of the MAC contract for Jurisdiction L (formerly known as Jurisdiction 12), and identifies Novitas as the MAC responsible for Jurisdictions L/12 since October 2007. This document is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Award-Background-J-L-Sept-2012.pdf>.

7. Novitas is also responsible for MAC Jurisdiction H, formerly known as Jurisdictions 4 and 7, which includes Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma and Texas. Novitas was awarded the contract for Jurisdiction H in late 2011, and has remained the MAC for that jurisdiction since that time. Attached as **Exhibit B** is a true and correct copy of the A/B MAC Jurisdiction H Award Fact Sheet, which describes the history of the MAC contract for Jurisdiction H (formerly known as Jurisdictions 4 and 7). This Fact Sheet states that CMS announced in November 2011, that Highmark was awarded the contract for Jurisdiction H. This document is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/Award-Background-J-H-Nov-2011.pdf>.

8. It is my understanding that Highmark changed its name to Novitas in or about January 2012, after Highmark was acquired by another organization. A notice dated March 2, 2012, describing this name change is attached as **Exhibit C**.

This notice is available on the CMS website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/UndocAliens/Section-1011-News-Archive-Items/2012-03-02-Novitas.html>.

9. Attached as **Exhibit D** is a true and correct copy of a printed screenshot from the CMS website providing additional information about the current MAC for Jurisdiction H. This page identifies Novitas as the MAC that has been responsible for Jurisdiction H since September 2011, and notes that the contract for Jurisdiction H was announced in November 2011 (consistent with the information included in Exhibit B). This page is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs-A-B-MAC-Jurisdiction-H-JH.html>.

10. In the absence of a National Coverage Determination or other binding policy identifying the circumstances in which Medicare will cover an item or service on a national basis, coverage decisions are generally made at the discretion of the MACs. MACs may issue Local Coverage Determinations (“LCD”) stating whether, and under what circumstances, a particular item or service may be covered by Medicare on a MAC-wide basis. MACs also convey information to health care providers on matters such as local exclusions or coding provisions through articles, bulletins and frequently asked questions (“FAQs”) posted on their websites.


11. On or about August 28, 2013, I visited the Novitas website relating to Jurisdiction H to obtain information regarding certain Medicare billing and coding issues involving anesthesia. Attached as **Exhibit E** is a true and correct copy of the anesthesia-related FAQs that I printed from the Novitas website at that time. The date that I accessed and printed these FAQs, August 28, 2013, is printed on the top right hand corner of each page of the document. The website address where I accessed the FAQs appears on the bottom left hand corner of each page of the document.

12. The handwriting and highlights that appear on the FAQs document are my own. I added these markings over the years in the course of advising various clients. I did not add any of these markings to the document in connection with this litigation.

13. I had been advised by one of my clients (not NAPA), that Novitas had removed anesthesia FAQs from its website, and in connection with signing this Declaration, I searched the Novitas website and could not locate any Anesthesia FAQs on the FAQ website, located at http://www.novitas-solutions.com/webcenter/portal/FAQs_JL?_adf.ctrl-state=mbp2101ff_42&_afrLoop=906470474123030#. I also performed a search of the website and could not locate this article.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: March 17, 2017

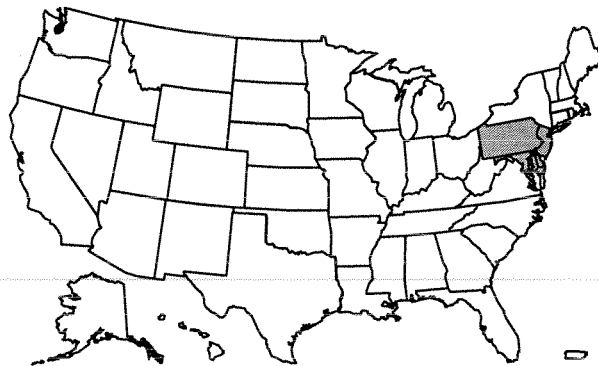


David M. Vaughn, Esq., CPC

EXHIBIT A

**Award of Part A/B (A/B) Medicare Administrative Contractor (MAC)
Contract for Jurisdiction L**

- On September 17, 2012, the Centers for Medicare & Medicaid Services (CMS) announced that Novitas Solutions, Inc. (Novitas) was awarded a new contract for the administration of Medicare Part A and Part B fee-for-service claims in the states of Delaware, Maryland, New Jersey, and Pennsylvania, as well as the District of Columbia (also known as A/B MAC Jurisdiction L).
- The new A/B MAC Jurisdiction L contract includes a base year and four option years, for a maximum duration of five years. The contract is a “cost plus award fee” contract; the award fee will be earned only if Novitas exceeds the base requirements of the contract.



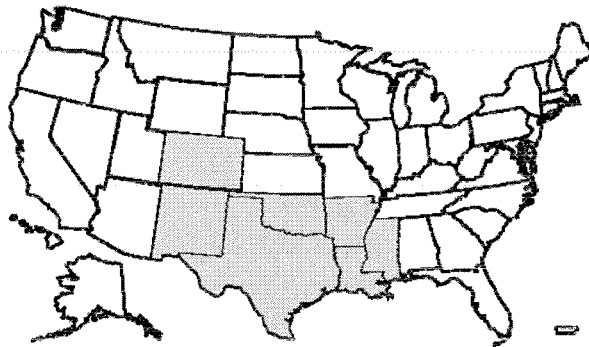
- Inclusive of all options, the newly-awarded contract has an estimated value of \$404.1 million. CMS issued the solicitation for the A/B MAC Jurisdiction L contract in January 2012.
- In addition to processing Part A and Part B claims in Jurisdiction L, Novitas will perform other critical Medicare fee-for-service operational functions, including enrolling, educating, and auditing Medicare providers.
- About 3.5 million Medicare fee-for-service beneficiaries reside in Jurisdiction L. Novitas will serve approximately 425 Medicare hospitals and about 86,000 physicians. Jurisdiction L comprises approximately 10.9% of the national Medicare fee-for-service Part A and Part B claims volume.
- Novitas currently services this Medicare workload under an A/B MAC contract that was awarded in October 2007 (when Jurisdiction L was known as Jurisdiction 12).
- As Novitas is the incumbent contractor for A/B MAC Jurisdiction 12 (to be known as Jurisdiction L), CMS anticipates that implementation of the new contract will go smoothly, with few disruptions in service for Medicare beneficiaries and providers.
- CMS has stringent standards for contract performance for Medicare claims administration contracts. CMS measures performance through a variety of processes, including on-site reviews, data validation reviews, and protocol-driven quality assurance reviews, as well as independent audits.
- As CMS continues to use the competitive process to select claims administration contractors, past performance and technical capability are major evaluation factors.

- Questions about the contract award should be directed to Edward B. Farmer, Jr. (“Chip”) in CMS’ Office of Acquisition and Grants Management. Mr. Farmer may be reached at 410-786-1997 or at Edward.Farmer@cms.hhs.gov.

EXHIBIT B

**Award of
Part A/B (A/B) Medicare Administrative Contractor (MAC)
Contract for Jurisdiction H**

- On November 8, 2011, the Centers for Medicare & Medicaid Services (CMS) announced that Highmark Medicare Services (HMS) has been awarded the contract for the administration of Medicare Part A and Part B fee-for-service claims in the newly-formed A/B MAC Jurisdiction H.
- CMS is forming Jurisdiction H by consolidating A/B MAC Jurisdictions 4 and 7. This change reflects the CMS MAC jurisdiction strategy, announced in 2010, to consolidate from 15 (fifteen) Part A/B MAC jurisdictions to 10 (ten) by 2016.
- When the new MAC contract is fully implemented, HMS will serve Medicare beneficiaries in Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas as reflected below.



- Over 4.9 million Medicare fee-for-service beneficiaries reside in Jurisdiction H. The new MAC, HMS, will serve approximately 1,300 Medicare hospitals and 147,000 physicians and other Part B providers. This jurisdiction comprises approximately 13.2% of the overall national Medicare fee-for-service Part A and Part B claims volume. CMS issued the solicitation for this contract in March 2011.
- The A/B MAC Jurisdiction H contract includes a base year and four option years, for a maximum duration of five years. The contract is a “cost plus award fee” contract; the award fee will be earned only if HMS exceeds the base requirements of the contract. Inclusive of all options, the awarded contract has a value of \$406 million.
- In addition to processing Part A and Part B claims in Jurisdiction H, HMS will perform other critical Medicare operational functions, including enrolling, educating, and auditing Medicare providers. HMS will also be responsible for some key specialty functions, including processing Indian Health Service facility claims for the entire country and serving as the designated A/B MAC to support centralized billing by immunization clinics.

- Over the next several months, CMS will oversee the transfer of Medicare work from the incumbent contractors noted below to HMS.
 - TrailBlazer Health Enterprises (TrailBlazer) is the incumbent contractor for A/B MAC Jurisdiction 4 (Colorado, New Mexico, Oklahoma, and Texas).
 - Pinnacle Business Solutions (Pinnacle) holds the Part A Fiscal Intermediary contracts for Arkansas, Louisiana, and Mississippi.
 - Pinnacle also holds the Part B carrier contracts for Arkansas and Louisiana.
 - Cahaba Government Benefits Administrators holds the Part B carrier contract for Mississippi.
- Barring any unforeseen delays, CMS expects to complete the transfer of the Medicare claims workloads for Arkansas, Louisiana, and Mississippi to HMS in early 2012. CMS expects to complete the transfer of the Colorado, New Mexico, Oklahoma, and Texas workloads (as well as Indian Health Service facilities) administered by TrailBlazer to the A/B Jurisdiction H MAC contract by late July 2012.
- CMS anticipates that implementation of the new contract will go smoothly, with few, if any, disruptions in service for Medicare beneficiaries and providers.
- Questions about the contract award should be directed to Kathy Markman in CMS' Office of Acquisition and Grants Management. Ms. Markman may be reached at 410-786-8916 or at Kathy.Markman@cms.hhs.gov.

Background on Medicare Contracting Reform

- In 2003, Congress mandated that CMS award contracts for Medicare fee-for-service claims administration services through competitive federal contracting processes.
- In 2005, CMS announced it would consolidate Medicare Part A and Part B fee-for-service claims administration into 15 (fifteen) regional jurisdictions. Eleven of these regional MAC jurisdictions are fully implemented, and the remaining four MACs are in progress.
- The competitive contracting provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 require that the MAC contracts be re-competed every five years. The award of MAC Jurisdiction H concludes the second re-competition of an A/B MAC contract. Further re-competitions of the initial set of MAC contracts are currently underway.
- In 2010, CMS announced the further consolidation of MAC jurisdictions from 15 (fifteen) Part A/B MAC jurisdictions to 10 (ten) by 2016. The first stage of this consolidation, to 13 (thirteen) MACs, will be accomplished in 2011. The Jurisdiction H A/B MAC contract is part of this consolidation strategy.
- CMS has stringent standards for contract performance on the MAC contracts and measures performance through a variety of processes, including on-site oversight, data reviews and protocol-driven quality assurance reviews, as well as independent audits.

- As CMS continues to use the competitive process to select claims administration contractors, the offerors' technical proposals as well as the past performance track records of the offerors are major evaluation factors. In the Jurisdiction H A/B MAC solicitation, CMS also designated implementation as an evaluation factor.

EXHIBIT C



Home > Regulations and Guidance > Section 1011 - Emergency Health Services Furnished to Undocumented Aliens > Section 1011 News Archive Items > Details for title: 2012-03-02

Details for title: 2012-03-02

Date 2012-03-02

Title Highmark Medicare Services, Inc. is becoming Novitas Solutions, Inc.

Highmark Medicare Services, Inc. is becoming Novitas Solutions, Inc.

Effective January 1, 2012, Diversified Service Options, Inc. (DSO), a wholly-owned subsidiary of Blue Cross and Blue Shield of Florida Inc., acquired Highmark Medicare from its parent company, Highmark Inc. As a result, HMS changed its name to Novitas Solutions, Inc. (Novitas). Novitas, pronounced Nō-va-tahs with an emphasis on the first syllable, is the Latin word for "newness", and we will be designing a new logo and brand management system to support the new company identity during the next few months.

Novitas will continue to be the Medicare Administrative Contractor (MAC) for JL and the Section 1011 Administrative Contractor. Our mission "to provide quality services and responsive solutions in the administration of our contracts according to our core values and in support of the goals of our stakeholders" remains unchanged. We will continue to provide the same great service with our knowledgeable and experienced staff to which you are accustomed.

As we move through the migration to our new name, Novitas will provide additional announcements and frequently asked questions (FAQs) on our Website that will cover any potential impacts to our customers. We will also announce changes to external documents and systems in advance. For example, our Website domain name will be changed in the near future to: <https://www.novitas-solutions.com/section1011> and we'll announce it in advance through a Web alert and listserv notice.

We appreciate your patience as we migrate to our new name.



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EXHIBIT D



[Home](#) > [Medicare](#) > [Medicare Administrative Contractors](#) > [Who are the MACs: A/B MAC Jurisdiction H \(JH\)](#)

Who are the MACs: A/B MAC Jurisdiction H (JH)

On this page:

- [Contract Award Information](#)
- [Contract Implementation Status and Schedule](#)
- [A/B MAC Jurisdiction H - Part A and Part B Facts](#)
- [Who were the former contractors in this jurisdiction?](#)

Contract Award Information

- Solicitation on FedBizOpps (FBO): [RFP-CMS-2011-0005](#), posted March 4, 2011
- Award Announcement: [A/B MAC Jurisdiction H award on FBO](#), November 8, 2011
- Contract Awardee: [Novitas Solutions, Inc.](#), contract number HHSM-500-2012-M0001Z
- [A/B MAC Jurisdiction H Award Fact Sheet](#) (September 2011)
- Anticipated Contract End Date: TBD

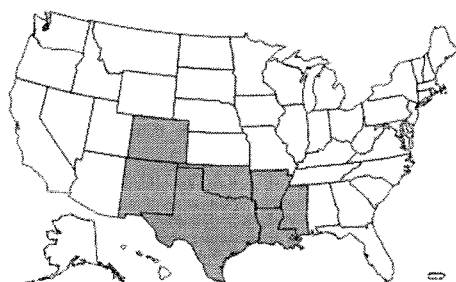
[return to top](#)

Contract Implementation Status and Schedule

- Fully implemented

[return to top](#)

A/B MAC Jurisdiction H - Part A and Part B Facts



- JH processes FFS Medicare Part A and Part B claims for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas
- Total Number of Fee-for-Service Beneficiaries: 5,717,831 (as of 09/30/2015)
- Total Number of Physicians: 116,095 (as of 09/30/2015)
- Total Number of Medicare Hospitals: 1,190 (as of 09/30/2015)
- Total Annual Claims Volume: 13.5% of national Part A/Part B workload

[return to top](#)

Who were the former contractors in this jurisdiction?

Learn about the former contractors in this jurisdiction at [Archives: A/B MAC Jurisdiction H](#).

[return to top](#)

Page last Modified: 02/05/2016 11:22 AM

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EXHIBIT E




FAQ's: NEXT pg

You are here : Home > Training & Events > Frequently Asked Questions

Frequently Asked Questions: Anesthesia

GENERAL

1. What guideline should a provider use to determine whether a specific service can or cannot be provided at the same time as medical direction? 
2. May an anesthesiologist perform preoperative evaluations for patients presenting for surgery later that day, or on future days?
3. May an anesthesiologist perform procedures on patients presenting for surgery that day, either preoperatively or in the post anesthesia care unit?
4. What constitutes the "immediate area of the operating suite"?
5. In the event that an anesthesiologist is medically directing one to four concurrent cases and, due to some intervening factor occurring, the medically directing anesthesiologist is unable to be present at emergence, is not immediately available for some portion of the case, or fails to note periodic monitoring on the chart, is it permissible to bill the case as "QZ" (CRNA service; without medical direction by a physician) as if the services were provided by a non-medically directed Certified Registered Nurse Anesthetists (CRNA) or Anesthesia Assistant (AA)?
6. Do you agree that there is no definable period of induction or emergence for Monitored Anesthesia Care (MAC) and regional anesthetic cases, and therefore the medically directing anesthesiologist need not indicate presence for induction and emergence for these cases?
7. May a medically directing anesthesiologist take a short break to eat a meal or use the rest room? What is a reasonable length of break time that could be provided by a Certified Registered Nurse Anesthetist (CRNA) to a physician who is personally administering a case without that case being medically directed? In a group practice, may the group bill for medical direction when the medically directing anesthesiologist is unable to be present for a key portion of a case, but another anesthesiologist within the group is present for the key portion of the case?

The following are questions and answers that provide a reasonable

36

interpretation of the existing Centers for Medicare and Medicaid Services (CMS) regulations regarding anesthesiology services performed concurrently with medical direction.

The general guidelines for concurrent services which may be performed along with medical direction are outlined in the Medicare Claims Processing Manual, Publication 100-4, Chapter12, Section 50C:

A physician who is concurrently directing the administration of anesthesia to not more than four surgical patients cannot ordinarily be involved in furnishing additional services to other patients. However, addressing an emergency of short duration in the immediate area, administering an epidural or caudal anesthetic to ease labor pain, or periodic, rather than continuous, monitoring of an obstetrical patient does not substantially diminish the scope of control exercised by the physician in directing the administration of anesthesia to surgical patients. It does not constitute a separate service for the purpose of determining whether the medical direction criteria are met. Further, while directing concurrent anesthesia procedures, a physician may receive patients entering the operating suite for the next surgery, check or discharge patients in the recovery room, or handle scheduling matters without affecting fee schedule payment.

However, if the physician leaves the immediate area of the operating suite for other than short durations or devotes extensive time to an emergency case or is otherwise not available to respond to the immediate needs of the surgical patients, the physician's services to the surgical patients are supervisory in nature. Carriers may not make payment under the fee schedule.

This section provides both general guidelines for allowable concurrent services and an illustrative list of services which, in the opinion of CMS, meet these guidelines. These general guidelines, however, have raised several significant questions from anesthesiologists. The following Q&A addresses those questions.

1. What guideline should a provider use to determine whether a specific service can or cannot be provided at the same time as medical direction?

A physician who is providing medical direction of anesthesia care cannot ordinarily provide additional services to other patients. However, guidelines describe the type of services the physician may provide, if the services do not prevent the physician from being immediately available to respond to the needs of surgical patients.

Date Posted: 10/07/2009, Date Revised: 07/15/2013


[Go to Top](#) 

2. May an anesthesiologist perform preoperative evaluations for patients presenting for surgery later that day, or on future days?

Yes. As long as the area in which the evaluations are performed is easily accessible from any area of the operating suite, the patient

services do not prevent the physician from being immediately available to address emergencies in the operating room, and most importantly, "do not substantially diminish the scope of control exercised by the physician in directing the administration of anesthesia to surgical patients," the anesthesiologist may perform pre-operative examinations concurrently while directing anesthesia care.

Date Posted: 10/07/2009, Date Revised: 07/15/2013

[Go to Top](#) 

3. May an anesthesiologist perform procedures on patients presenting for surgery that day, either preoperatively or in the post anesthesia care unit?

An anesthesiologist may perform, and if otherwise eligible seek reimbursement for, procedures (such as arterial line insertions, central venous catheter insertions, pulmonary artery catheter insertions, and epidural, spinal, and peripheral nerve blocks) in an area that is immediately available to the operating room, and when the performance of such services do not prevent him/her from being immediately available to respond to the needs of the surgical patients.

Date Posted: 10/07/2009, Date Revised: 07/15/2013

[Go to Top](#) 

4. What constitutes the "immediate area of the operating suite"?

Differences in the geographic design and size of facilities, differences in the severity of illness, and the complexity and demands of the particular surgical procedures make this distance impossible to universally define. That said, the anesthesiologist must remain close enough to the operating room to return to the operating room, if/when needed, in time to meet the needs of the patient, and most importantly, emergencies that may arise.

Date Posted: 10/07/2009, Date Revised: 07/15/2013

[Go to Top](#) 

5. In the event that an anesthesiologist is medically directing one to four concurrent cases and, due to some intervening factor occurring, the medically directing anesthesiologist is unable to be present at emergence, is not immediately available for some portion of the case, or fails to note periodic monitoring on the chart, is it permissible to bill the case as "QZ" (CRNA service; without medical direction by a physician) as if the services were provided by a non-medically directed Certified Registered Nurse Anesthetists (CRNA) or Anesthesia Assistant (AA)?

Medicare agrees that services of the anesthetist in question should be billed as non-medically directed or "QZ." The "-QZ" modifier is utilized to denote the service was provided by a CRNA without medical direction by a physician.

Date Posted: 10/07/2009, Date Revised: 07/15/2013

[Go to Top](#) 

6. Do you agree that there is no definable period of induction or emergence for Monitored Anesthesia Care (MAC) and regional anesthetic cases, and therefore the medically directing anesthesiologist need not indicate presence for induction and emergence for these cases?

Medicare agrees the medically directing physician participates in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence. Medicare would expect the medically directing anesthesiologist to indicate continuous availability for the MAC or regional anesthetic case in the record and to provide monitoring as indicated, but would not expect any notation regarding induction or emergence, since these terms have no meaning for MAC or regional cases.

Date Posted: 10/07/2009, Date Revised: 07/15/2013

[Go to Top](#) 

7. May a medically directing anesthesiologist take a short break to eat a meal or use the rest room? What is a reasonable length of break time that could be provided by a Certified Registered Nurse Anesthetist (CRNA) to a physician who is personally administering a case without that case being medically directed? In a group practice, may the group bill for medical direction when the medically directing anesthesiologist is unable to be present for a key portion of a case, but another anesthesiologist within the group is present for the key portion of the case?

The above questions pertain to the care and safety of the patient. The State Operations Manual, Publication 100-07, Appendices A-1000 (Condition of Participation: Anesthesia Services) advises that it is the responsibility of the hospital to ensure that "the anesthesia service must be organized and staffed in such a manner as to ensure the health and safety of patients." Therefore, breaks and the sharing of a case by anesthesiologists within a group are eligible under Medicare when the Medicare guidelines are met and when the care meets the safety standards established by the hospital.

Date Posted: 04/26/2011, Date Revised: 07/15/2013

[Go to Top](#) 



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40